

August 26, 2016  
SymBio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
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(Securities Code: 4582)

### **Approval of the Anti-cancer Drug TREAKISYM® for the Additional Indication of Chronic Lymphocytic Leukemia**

TOKYO, Japan, August 26, 2016 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announced today that the anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride; "the Product") is now approved for the additional indication of chronic lymphocytic leukemia.

SymBio has developed and applied for this indication upon request of the Ministry of Health, Labour and Welfare as one of the "unapproved or off-label drugs with high medical needs." SymBio has already received marketing and manufacturing approval for the indication of recurrent/refractory low-grade malignant non-Hodgkin's lymphoma and mantle cell lymphoma in October, 2010.

SymBio has marketed the Product through Eisai Co., Ltd. since December, 2010 and its current market share is about 60% for the indication of recurrent/refractory low-grade malignant non-Hodgkin's lymphoma and mantle cell lymphoma, as estimated by SymBio. The Product is now expected to offer a new treatment option for many patients with chronic lymphocytic leukemia.

In addition to these indications, in December, 2015, SymBio submitted a J-NDA for the first-line treatment of low-grade malignant non-Hodgkin's lymphoma and mantle cell lymphoma, which is currently being reviewed by the Pharmaceuticals and Medical Devices Agency. Also, a Phase 2 study in patients with recurrent/refractory advanced aggressive malignant non-Hodgkin's lymphoma has been completed.

SymBio will pursue expanded indications and the full range of use of the Product in an effort to maximize its value.

The approval of this chronic lymphocytic leukemia indication will not impact the current financial forecast.

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### **About chronic lymphocytic leukemia (CLL)**

CLL is a cancer of the blood characterized by the progressive accumulation of functionally incompetent lymphocytes, a type of white blood cell produced by the bone marrow and organs of the lymphatic system. The number of CLL patients in Japan is estimated to be around 2,000. In the U.S. and EU, bendamustine has been approved for the treatment of CLL where the disease accounts for an estimated 30% of all leukemia cases. Due to the lack of effective therapies in Japan, CLL patients are seriously underserved and a high unmet medical need exists for the development of an effective alternative therapy.

### **Overview of TREAKISYM® (The underlined section is newly approved.)**

Product name: TREAKISYM® for injection, for intravenous infusion 100 mg

Generic name: Bendamustine hydrochloride

Indications and usage: For the treatment of relapsed or refractory forms of the following diseases

1. Low-grade B-cell non-Hodgkin's lymphoma

Mantle cell lymphoma

#### 2. Chronic lymphocytic leukemia

Dosage and administration:

1. Low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma

The recommended adult dose is bendamustine hydrochloride 120 mg/m<sup>2</sup> (body surface area) via 1-hour intravenous infusion once daily for 2 days on treatment, followed by 19 days off treatment, with repeated cycles. Dosage may be reduced as appropriate in accordance with the patient's condition.

#### 2. Chronic lymphocytic leukemia

The recommended adult dose is bendamustine hydrochloride 100 mg/m<sup>2</sup> (body surface area) via 1-hour intravenous infusion once daily for 2 days on treatment, followed by 26 days off treatment, with repeated cycles. Dosage may be reduced as appropriate in accordance with the patient's condition.

### **About SymBio Pharmaceuticals Limited**

SymBio Pharmaceuticals Limited was established in March, 2005 by Fuminori Yoshida who previously served concurrently as Corporate VP of Amgen Inc. and founding President of Amgen Japan. In May, 2016 the Company incorporated its wholly-owned subsidiary in the U.S., called SymBio Pharma USA, Inc. (Headquarters: Menlo Park, California, President: Mr. Fuminori Yoshida). The Company's underlying corporate mission is to "deliver hope to patients in need" as it aspires to be a leading global specialty biopharmaceutical company dedicated to addressing underserved medical needs with main therapeutic focus in oncology, hematology and pain management.